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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------------|-------------------------------|----------------------|---------------------|------------------|
| 10/062,308 | 02/01/2002 | David L. Rimm | YUA-001.01 | 2553 |
| 25181 | 7590 04/07/2005 | | EXAMINER | |
| FOLEY HOAG, LLP MAHATAN, CHANN | | | | CHANNING |
| PATENT GR 155 SEAPOR | OUP, WORLD TRADE C RT BLVD | ENTER WEST | ART UNIT | PAPER NUMBER |
| BOSTON, M | 1A 02110 | | 1631 | - |
| | | | | _ |

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|--|---|---|------------|--|--|--|
| Office Action Cumment | 10/062,308 | RIMM ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Channing S. Mahatan | 1631 | | | | |
| The MAILING DATE of this communication Period for Reply | appears on the cover sheet wit | h the correspondence address | \$ | | | |
| A SHORTENED STATUTORY PERIOD FOR RE THE MAILING DATE OF THIS COMMUNICATIO - Extensions of time may be available under the provisions of 37 CFF after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a - If NO period for reply is specified above, the maximum statutory per - Failure to reply within the set or extended period for reply will, by state of the period for reply will be stated by the Office later than three months after the mean part of the period for reply will be set of the period for reply will be stated by the Office later than three months after the mean period for reply will be set of the period for reply will be set of the period for reply will be set or extended period for reply | N. R 1.136(a). In no event, however, may a re reply within the statutory minimum of thirty riod will apply and will expire SIX (6) MON atute, cause the application to become AB | eply be timely filed (30) days will be considered timely. FHS from the mailing date of this communication ANDONED (35 U.S.C. § 133). | lication. | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on 2 | 7 January 200 <u>5</u> . | | | | | |
| | This action is non-final. | | | | | |
| | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | | |
| <u> </u> | he annlication | | | | | |
| • | ✓ Claim(s) <u>1-32 and 39-43</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| · <u> </u> | | | | | | |
| 7)⊠ Claim(s) <u>17 and 23-29</u> is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction an | d/or election requirement. | | ļ | | | |
| Application Papers | | | | | | |
| <u> </u> | · | | | | | |
| | 9) The specification is objected to by the Examiner. | | | | | |
| | 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| The pain of declaration is objected to by the | Examiner. Note the attached | Office Action of John PTO-15 |)2. | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for fore a) All b) Some * c) None of: 1. Certified copies of the priority docum 2. Certified copies of the priority docum 3. Copies of the certified copies of the priority docum | ents have been received. ents have been received in Appriority documents have been | oplication No | e | | | |
| | application from the International Bureau (PCT Rule 17.2(a)). | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | | | | | | |
| Attachment(s) | | | | | | |
| 1) ⊠ Notice of References Cited (PTO-892) 2) ☑ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4) ∐ Interview St Paper No(s` | ummary (PTO-413) /Mail Date | | | | |
| Notice of Bransperson's Faterit Brawing Review (FT0-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/Paper No(s)/Mail Date | | formal Patent Application (PTO-152) |) | | | |

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DETAILED ACTION

PROSECUTION IS REOPENED

Based upon Applicants' arguments, filed 27 January 2005, prosecution of this application is reopened to introduce new grounds of rejection as set forth below. The newly applied rejections have resulted in the withdrawal of the finality of the previous office action mailed 16 June 2004. For this reason, the current action will be non-final. Additionally, the 'Notice of Appeal' filed 20 December 2004 is now moot. Finally, Applicants amendment filed 27 January 2005 has been entered.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-32 and 39-43. Claims 33-38 are withdrawn from examination as directed to a non-elected invention.

Claims Rejected Under 35 U.S.C. 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claims 21 and 22 recite the limitations "a largest bin" and "a second largest bin", respectively, which is considered vague and indefinite. The above limitations appear to imply a range of largest bins such that "a largest bin" and "a second largest bin". It should be noted the language "the largest bin" and "the second largest bin" makes clear that no range of largest bins

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exists, for example, an individual bin which is the largest is considered to be the largest bin. Clarification of the metes and bounds, via clearer claim language is requested.

LACK OF ANTECEDENT BASIS

Claim 18 and all claim dependent therefrom recites the limitation "in the mask set" which appears to lack proper antecedent basis. While it is acknowledged claim 17 (which claim 18 depend from) recites the step of "assigning pixel locations to a mask based on the threshold intensity value" no "mask set" is indicated. Clarification of the metes and bounds, via clearer claim language, is requested.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8 and 30-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Harari et al. (Pub. No. US 2002/0067409 A1).

Harari et al. discloses a data acquisition and display system applicable to all types of image gathering techniques and that such high precision devices utilize CCD technology (i.e. pixels)(instant claims 2, 3, & 5; Abstract; and Paragraph [0004]). The inventors provide that the images acquired from a first and second image are superimposed one on another for simultaneous visualization (instant claim 1; Paragraphs [0008] & [0045]; and Figure 1). Harari

invention.

et al. indicates that different sets of conditions may be applied, which include variations in illumination method, filters, applied stain or marker, plane of focus or depth of focus (instant claims 7, 8, & 31; Paragraphs [0016] & [0138] to [0140]; and Figure 5 "multiple images"). Harari et al. indicates the application of the disclosed invention to the analysis of biological samples (i.e. cells, tissues) to visualize transmittance (i.e. intensity) of stains & markers within a cell(s) (instant claims 1-8; Paragraph [0150]). Further, the authors disclose the function of deleting background color (i.e. distribution of 100% intensity value) from acquired images so that two images may be placed upon one another to appear as a mix of the two colors (instant

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Claims Rejected Under 35 U.S.C. § 103

claims 30 & 32; Paragraph [0111]). Thus, Harari et al. anticipates the instantly claimed

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-16, 30-32, and 39-43 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Harari et al. (Pub. No. US 2002/0067409 A1) taken in view of Dunlay et al. (U.S. Patent Number 6,727,071).

Harari et al. is herein applied from above (instant claims 1-8; Refer to 35 U.S.C. § 102(e) rejection). It should be noted the Harari et al. indicates that biological samples (i.e. cells & tissues) are in many cases stained (i.e. fixed) prior to analysis (instant claims 39-43; Paragraph

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[0150]). However, Harari et al. fails to provide for various stains for labeling sub-cellular compartments.

Dunlay et al. discloses systems, methods, and screens for an optical system analysis of cells to rapidly determine the distribution, environment, or activity of fluorescently labeled reporter molecules in cells by combining many cell screening formats with fluorescence-based molecular reagents and computer-based feature extraction, data analysis, and automation thereby significantly improve target validation and candidate optimization (Abstract; and Column 5, lines 28-40). The inventors disclose various methodologies for labeling cellular compartments applicable to the disclosed invention, such methodologies include whole cell labeling (column 39, lines 28-56), plasma membrane labeling (columns 39-40, lines 57-67 and 1-45, respectively); endosome fluorescent labeling (column 40, lines 46-64), lysome labeling (columns 40-41, lines 65-67 and 1-22, respectively), cytoplasmic fluorescence labeling (columns 41-42, lines 23-67 and 1-16), nuclear labeling (column 42, lines 17-45), mitochondria labeling (column 42-43, lines 46-67 and 1-9, respectively), endoplasmic reticulum labeling (column 43, lines 10-31), and golgi labeling (column 43, lines 32-52) (instant claims 9-16).

Thus, it would have been obvious to one of skill in the art at the time of the invention to combine the data acquisition and display system of Harari et al. with various sub-cellular compartment stains of Dunlay, thereby performing multiple staining, multiple image acquisition, and multiple image analysis. Since, Harari et al. states that "it is advantageous to co-stain a single sample with one or more conventional stains and one or more fluorescent stains" (instant claims 11 and 14; page 7, left column, lines 36-54) and that "variations and modifications thereof which would occur to persons skilled in the art upon reading the foregoing description" (page 7,

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right column, lines 5-7). Further, Dunlay et al. indicates that the provided examples were intended for illustration only and one in the art would "recognize a wide variety of distinct screens that can be developed based on the disclosure provided" (Column 43, lines 63-65).

ALLOWABLE CLAIMS

Claims 17 and 23-29 would be allowable if rewritten or amended to independent form and to include all of the limitations of the base claim and any intervening claims.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either 571-273-8300.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify Applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables Applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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Examiner Initials: CSW

Date: April 3, 2005

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